

REMARKS

The Office Action mailed July 2, 2002, set a three-month shortened statutory period for response expiring October 2, 2002. The period for response is extended three months to January 2, 2003, pursuant to the Petition for Extension of Time under 37 C.F.R. 1.136(a) submitted herewith. This response is therefore timely filed.

The specification is amended by replacing the Sequence Listing in both the paper copy and the computer readable copy with a corrected sequence. During the preparation of PCT/FR96/01756 from the French priority application 95/14424, an incorrect sequence was inadvertently introduced as SEQ ID NO: 1. The corrected sequence corresponds to the nucleotide sequence shown in Figs. 2A and 2B and described at page 23, line 34 to page 24, line 5 of the instant application as filed and to SEQ ID NO: 1 of priority French application 95/14424, a certified copy and sworn translation of which were submitted in this application on May 8, 2000. Hence, no new matter is introduced by the amendment of the Sequence Listing or by substitution of the computer readable form thereof. The substitute computer readable form is the same as the Sequence Listing as amended.

Claims 5-36, 38, and 44-114 are in the application. Claims 5-36, 38, 52-71, and 89-110 are withdrawn from consideration as drawn to non-elected subject matter. Claims 44-51, 72-88, and 111-114 are under examination.

Claims 72-88 and 111-114 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Claims 72, 83, and 87 are held to be indefinite on the grounds that the language “biologically active fragment” and “having the ability to bind IL-13” are unclear. The Examiner suggests amending “having the ability to bind IL-13” to read “binds” to overcome the rejection. Claims 72, 83, and 87 are amended accordingly and hence the rejection is believed overcome.

Claims 78-111 are held to be indefinite on the basis that the terms “allelic variant” and “stringent conditions” are unclear. It is submitted that the terms “allelic variant” and “stringent conditions” would be readily understood by one skilled in the art. The term “allelic variant” is recognized and accepted by the PTO as evidenced by the issuance of U.S. Patents 5,710,023 (column 5, lines 5-10, and claim 1) and 6,268,480 (column 5, lines 12-17, and claim 13) which use that term. Thus, in the context of the instant case, “allelic variant” would mean a naturally occurring variant of the nucleotide sequence encoding the IL-13 receptor. Copies of the ‘023

and '480 patents are enclosed herewith for the Examiner's convenience. Regarding the term "stringent conditions", as explained at page 8, lines 5-7 and 25-28 of the specification, appropriate hybridization conditions are those customarily employed by those skilled in the art, as more particularly described at lines 8-12. Accordingly, claims 78-111, read in light of the specification, are not indefinite. Reconsideration of the rejection is requested.

Claim 87 is held to be indefinite on the grounds that the meanings of the "mature sequence" of IL-13R β , and the "extracellular" and "intracytoplasmic" domains are unclear. As pointed out at page 7, lines 27-28, the mature protein results from the release of the signal peptide which is indicated in italics in Fig. 2A (specification, page 14, lines 15-16). The extracellular domain is described at page 6, lines 19-21, as stretching to residue 343, and the intracytoplasmic tail follows the transmembrane domain which is indicated in bold characters in Fig. 2B (specification, page 24, lines 4-5, and page 14, lines 17-18). Thus, the terms that form the basis for the rejection are clearly described. The Examiner further maintains that reference in the claim to "sequence (1)" is unclear. Claim 87 is amended to replace "(1)" with --a-- correcting an inadvertent error in which the first Markush Group member, IL-13R β , is referred to as the sequence referred to in clause (1) (as had been done in prior claims, e.g., claims 78 and 79) rather than the sequence referred to in clause (a). Thus, it is submitted that claim 87 as amended is in full compliance with the requirements of 35 U.S.C. § 112 and the rejection thereof should be withdrawn.

Claim 111 is held to be indefinite on the grounds that it is not clear which sequence is being referred to therein. While Applicants maintain that the sequence referred to is unambiguously described by Figs. 2A and 2B, in order to advance prosecution, the claims have been amended to replace "Figs. 2A and 2B" with --SEQ ID NO: 1--.

Inasmuch as the rejection under 35 U.S.C. § 112 of claims 72, 83, 87, and 111 as being indefinite is overcome by the foregoing amendments and remarks, said rejection is likewise overcome for claims 73, 77-82, 84-86, 88, and 112-114, which ultimately depend from claims 72, 83, 87, and 111.

The rejection of claims 48-51, 74, 85, and 88 under 35 U.S.C. § 112, first paragraph, for reasons of record is rendered moot by the cancellation of said claims. Claims 48-51, 74, 85, and 88 are cancelled herein without prejudice to the prosecution thereof in a continuing application.

Claims 44, 46-51, 72-81, 83-88, and 111-114 are newly rejected under 35 U.S.C. § 112, first paragraph, apparently on the grounds that the specification, while being enabling for the protein comprising SEQ ID NO: 2, does not provide enablement for other proteins. Applicants respectfully point out that claims 44, 46, 47, 79, and 80 are directed to one or more of the proteins of SEQ ID NO: 2, SEQ ID NO: 2 in which the 8 c-terminal residues are substituted by the 6 residues of SEQ ID NO: 11, SEQ ID NO: 2 from residue 1-343 and SEQ ID NO: 2 from residue 1-337. These proteins and the use thereof are clearly described in the specification e.g., in SEQ ID NO: 2 and Fig. 2A and 2B, and in the specification at page 6, lines 14-21; at Example 6, which describes the preparation of the polypeptide of SEQ ID NO: 2 from residues 1-337; and in Figs. 5 and 6, which show the use thereof in the inhibition of IL-13 binding. Thus, at least as regards claims 44, 46, 47, 79, and 80, the rejection is submitted to be without merit and should be withdrawn. Likewise, claims 73, 75, 84, and 86 are directed to specifically defined fragments of SEQ ID NO: 2, and accordingly, the rejection of those claims should also be withdrawn.

Claims 72, 76-78, 81, 83, and 87 are directed to specifically defined amino acid sequences and/or to biologically active fragments or allelic variants thereof. The specification at page 5, lines 6-16 clearly defines the term “biologically active”. Moreover the terms “biologically active” and “allelic variant” are recognized and accepted by the PTO as evidenced by U.S. Patents 5,710,023 (column 4, lines 53-65; column 5, lines 5-10; claims 1 and 11); 6,248,714 (column 4, line 58-column 5, line 3; column 5, lines 10-15; claim 6); and 6,268,480 (column 4, line 60-column 5, line 5; column 5, lines 12-17; claims 1 and 13) the pertinent disclosures of which do not differ substantially from the instant disclosure. Copies of the ‘023, ‘714, and ‘480 patents are enclosed herewith for the Examiner’s convenience. Issuance of these patents confirms that “biologically active” fragments and “allelic variants” are enabled therein, and hence are likewise enabled in the instant application. Accordingly, one skilled in the art would know how to make and use such “biologically active” fragments or “allelic variants” without undue experimentation.

Claims 44, 45, 47, 72, 73, 75, 77-84, 86-87, and 111-114 are rejected under 35 U.S.C. § 102(b) as being anticipated by Vita et al. on the grounds that the polypeptide disclosed by Vita et al. possesses the same activity as SEQ ID NO: 2, is from the same organism, and has an apparent molecular weight comparable to that disclosed in the instant specification. The rejection is respectfully traversed and reconsideration thereof is requested.

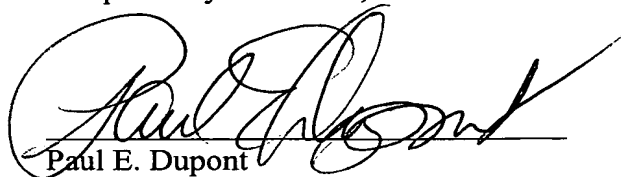
Applicants' claims are directed to purified IL-13 receptor polypeptides of specified amino acid sequences. Vita et al. do not disclose any amino acid sequences. Moreover, Fig. 4B referred to by the Examiner shows radioautographs of complexes of labeled IL-13 GYGY bound to a ligand or ligands of unknown structure in A431 cells. Moreover, in the discussion of Fig. 4, it is stated that the nature of the protein that yields the 70 kD complex is not clear (page 3514, right column.) In fact, the reference points out that the results of the reported studies suggest that the IL-13 receptor may be constituted by a subset of the IL-4 receptor complex associated with at least one additional protein (page 3512, left column), and that the IL-13 receptor is yet to be identified (page 3517, left column, third paragraph, last sentence).

The Examiner urges that the protein of Vita et al. is both isolated and purified. Applicants disagree. Vita et al. disclose a radioautograph of a complex of undisclosed purity produced by crosslinking a labeled structurally modified IL-13 GYGY with a ligand or ligands of undisclosed structure. Surely, this streak on a radioautograph of a radiolabeled complex of unknown structure does not amount to a disclosure of the isolated, purified polypeptide of SEQ ID NO: 2, and cannot be fairly construed as placing it in the public's possession. Accordingly, it is submitted that Vita et al. is incompetent as a reference under 102(b) and the rejection based thereon should be withdrawn.

Attached hereto is a marked-up version of the changes made to the claims by the instant amendment. The marked-up version is entitled "Version With Markings To Show Changes Made".

In view of the foregoing, this application is believed in condition for favorable reconsideration and such action is earnestly solicited.

Respectfully submitted,



Paul E. Dupont
Reg. No. 27,438

Date: 12/19/02

Address:
Sanofi-Synthelabo Inc.
9 Great Valley Parkway
Malvern, PA 19355
Tele: (610) 889-6338
Facsimile: (610) 889-8799

Version With Markings To Show Changes Made

In the specification:

The Sequence Listing following page 36 and computer readable form thereof have been replaced by a corrected Sequence Listing on replacement sheets 37-47 and a corrected computer readable copy.

In the Claims:

72. (Amended) An isolated IL-13bc (IL13R β) protein comprising an amino acid sequence selected from the group consisting of:

- (a) the amino acid sequence of SEQ ID NO: 2;
- (b) the amino acid sequence of SEQ ID NO: 2 from amino acids 26 to 341;
- (c) the amino acid sequence of SEQ ID NO: 2 from amino acids 363 to 380; and
- (d) fragments of (a)-(c) ~~having the ability to~~ which bind IL-13 or a biologically active fragment thereof.

78. (Amended) A protein produced according to a process comprising:

- (a) growing a culture of a host cell in a suitable culture medium; and
- (b) purifying the protein from the culture,

wherein said host cell is transformed with a polynucleotide operably linked to an expression control sequence, and wherein said polynucleotide comprises a nucleotide sequence selected from the group consisting of

- (1) a nucleotide sequence encoding the amino acid sequence of SEQ ID 2;
- (2) a nucleotide sequence encoding the IL-13R β binding chain varying from the sequence of the nucleotide sequence ~~specified in (1)~~ encoding the amino acid sequence of SEQ ID NO: 2 as a result of degeneracy of the genetic code; and
- (3) a nucleotide sequence capable of hybridizing under stringent conditions to a nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 2 ~~(1)~~; and

(4) an allelic variant of the nucleotide sequence ~~specified in (1)~~ encoding the amino acid sequence of SEQ ID NO: 2.

79. (Amended) The protein of claim 78, wherein said nucleotide sequence is that of ~~(1)~~ a nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 2.

80. (Amended) The protein of claim 78, wherein said nucleotide sequence ~~is that of (2)~~ encodes the IL-13R β binding chain varying from the sequence encoding the amino acid sequence of SEQ ID NO: 2 as a result of the degeneracy of the genetic code.

83. (Amended) An isolated IL-13R β protein comprising an amino acid sequence selected from the group consisting of:

- (a) the amino acid sequence of SEQ ID NO: 2;
- (b) the amino acid sequence of SEQ ID NO: 2 from amino acids 23 to 342;
- (c) the amino acid sequence of SEQ ID NO: 2 from amino acids 365 to 380; and
- (d) fragments of (a)-(c) ~~having the ability to~~ which bind IL-13 or a biologically active fragment thereof.

87. (Amended) An isolated IL-13R β protein comprising an amino acid sequence selected from the group consisting of:

- (e) the mature sequence of the IL-13 receptor chain protein, IL-13R β ;
- (f) the extracellular domain of sequence ~~(1)~~ (a); and
- (g) the intracytoplasmic domain sequence of ~~(1)~~ (a).
- (h) fragments of (a)-(c) ~~having the ability to~~ which bind IL-13 or a biologically active fragment thereof.

111. (Amended) A protein produced according to a process comprising:

- (a) growing a culture of a host cell in a suitable culture medium; and
- (b) purifying the protein from the culture,

wherein said host cell is transformed with a polynucleotide operably linked to an expression control sequence, and wherein said polynucleotide comprises a nucleotide sequence selected from the group consisting of

- (1) the nucleotide sequence of ~~Fig. (2A and 2B)~~ SEQ ID NO: 1 from nucleotide 53 to nucleotide 1192;
- (2) a nucleotide sequence encoding the IL-13R β binding chain varying from the sequence of ~~the nucleotide sequence specified in (1)~~ SEQ ID NO: 1 from nucleotide 53 to nucleotide 1192 as a result of degeneracy of the genetic code;
- (3) a nucleotide sequence capable of hybridizing under stringent conditions to the nucleotide sequence of SEQ ID NO: 1 from nucleotide 53 to nucleotide 1192 ~~(1)~~; and
- (4) an allelic variant of the nucleotide sequence ~~specified in (1)~~ of SEQ ID NO: 1 from nucleotide 53 to nucleotide 1192.

112. (Amended) The protein of claim 111, wherein said nucleotide sequence comprises the nucleotide sequence of SEQ ID NO: 1 from nucleotide 53 to nucleotide 1192 ~~that of (1)~~.

113. (Amended) The protein of claim 111, wherein said nucleotide sequence comprises a nucleotide sequence encoding the IL-13R β binding chain varying from the sequence of SEQ ID NO: 1 from nucleotide 53 to nucleotide 1192 as a result of degeneracy of the genetic code ~~that of (2)~~.

Claims 48-51, 74, 85, and 88 have been cancelled.